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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,529	11/28/2001	Kimberly A. Gillis	102729-14	3553

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/996,529	<b>Applicant(s)</b> GILLIS ET AL.	
	<b>Examiner</b> MINH-TAM DAVIS	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-35 are pending in the application and are currently under prosecution.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Claim 1 is a linking claim, linking groups 1-6. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups 1-3**, claims 1-7, 11-16, drawn to a method for detecting prostate cancer, comprising measuring the mRNA level of ID1 or ID3 or a combination of ID markers, classified in class 435, subclass 6. A method measuring the mRNA level of each ID marker, or a combination of ID markers constitutes a single distinct invention.

**Groups 4-6**, claims 1, 3-10, drawn to a method for detecting prostate cancer, comprising measuring the protein level of ID1 or ID3 or a combination of ID markers,

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classified in class 435, subclass 7.1. A method measuring the protein level of each ID marker, or a combination of ID markers constitutes a single distinct invention.

Claim 17 is a linking claim, linking groups 7-12. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups 7-9**, claims 17-21, drawn to a method for monitoring the progression of prostate cancer, comprising measuring the mRNA level of ID1 or ID3 or a combination of ID markers, classified in class 435, subclass 6. A method measuring the mRNA level of each ID marker, or a combination of ID markers constitutes a single distinct invention.

**Groups 10-12**, claims 17, 19-21, drawn to a method for monitoring the progression of prostate cancer, comprising measuring the protein level of ID1 or ID3 or a combination of ID markers, classified in class 435, subclass 7.1. A method measuring

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the protein level of each ID marker, or a combination of ID markers constitutes a single distinct invention.

Claims 22, 35 are linking claims, linking groups 13-16. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claims 22, 35. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups 13-14**, claims 22, 35, drawn to a method for assessing the efficacy of treating prostate cancer, comprising measuring the mRNA level of ID1 or ID3 markers, classified in class 435, subclass 6. A method measuring the mRNA level of each ID marker constitutes a single distinct invention.

**Groups 15-16**, claims 22, 35, drawn to a method for assessing the efficacy of treating prostate cancer, comprising measuring the protein level of ID1 or ID3 markers,

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classified in class 435, subclass 7.1. A method measuring the protein level of each ID marker constitutes a single distinct invention.

Claim 23 is a linking claim, linking groups 17-20. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups 17-18**, claim 23, drawn to a method for assessing the potential of a test compound to trigger prostate cancer, comprising measuring the mRNA level of ID1 or ID3 markers, classified in class 435, subclass 6. A method measuring the mRNA level of each ID marker constitutes a single distinct invention.

**Groups 19-20**, claim 23, drawn to a method for assessing the potential of a test compound to trigger prostate cancer, comprising measuring the protein level of ID1 or

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ID3 markers, classified in class 435, subclass 7.1. A method measuring the protein level of each ID marker constitutes a single distinct invention.

Claim 24 is a linking claim, linking groups 21-22. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 24. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups 21-22**, claim 24, drawn to a method for treating prostate cancer, comprising delivering/administering ID1 or ID3 protein, classified in class 514, subclass 2. A method for treating prostate cancer, comprising administering either ID1 or ID3 protein constitutes a single distinct invention.

**Groups 23-24**, claim 25, drawn to a method for treating prostate cancer, comprising expressing ID1 or ID3 protein by an expression vector, classified in class

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514, subclass 44. A method for treating prostate cancer, comprising expressing either ID1 or ID3 protein constitutes a single distinct invention.

Claim 26 is a linking claim, linking groups 25-28. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 26. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**Groups 25-26**, claims 26-27, 29, drawn to a method for identifying a compound useful for treating prostate cancer, comprising measuring the mRNA level of ID1 or ID3 markers in the presence or absence of said compound, classified in class 435, subclass 6. A method measuring the mRNA level of each ID marker constitutes a single distinct invention.

**Groups 27-28**, claims 26, 28-29, drawn to a method for identifying a compound useful for treating prostate cancer, comprising measuring the protein level of ID1 or ID3



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markers in the presence or absence of said compound, classified in class 435, subclass 7.1. A method measuring the protein level of each ID marker constitutes a single distinct invention.

**Groups 29-30**, claims 30-31, drawn to a method for identifying a compound useful for treating prostate cancer, comprising measuring the activity of ID1 or ID3 markers in the presence or absence of said compound, classified in class 435, subclass 7.1. A method measuring the activity of each ID marker constitutes a single distinct invention.

Claim 32 is a linking claim, linking groups 31-34. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 32. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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**Groups 31-32**, claims 32-33, drawn to a method for treating prostate cancer, comprising administering a compound which increases the mRNA level of ID1 or ID3, classified in class 514, subclass 44. A method comprising administering a compound which increases the mRNA level of either ID1 or ID3 constitutes a single distinct invention.

**Groups 33-34**, claims 32, 34, drawn to a method for treating prostate cancer, comprising administering a compound which increases the protein level of ID1 or ID3, classified in class 514, subclass 44. A method comprising administering a compound which increases the protein level of either ID1 or ID3 constitutes a single distinct invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-34 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement could be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'M. Davis' or similar, located at the bottom left of the page.

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MINH TAM DAVIS

PATENT EXAMINER

February 06, 2004